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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,496	12/10/2001	H. William Harris	2856.1001-011	7764

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EXAMINER

BASI, NIRMAL SINGH

ART UNIT PAPER NUMBER

1646

DATE MAILED: 01/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,496	HARRIS ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/3/04 and 7/26/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restriction***

1. Applicant's election without traverse of Group I (Claims 1-8) drawn to the polypeptide disclosed in SEQ ID NO:2, which is encoded by the polynucleotide disclosed in SEQ ID NO: is acknowledged. The traversal is on the ground(s) that the election of the polypeptide is a requirement for an election of species. Applicants state they do not understand the Examiners statements in the first full paragraph on page 6. Applicant's arguments have been fully considered and the Restriction is further clarified. On page 6 of the Restriction requirement dated October 6, 2004, the examiner stated that the claims of the different group are drawn to a multitude of polypeptides of SEQID NO:2, 4, 6, 8, 10 and 12, encoded by the nucleic acid of SEQ ID NO:1, 3, 5, 7, 9 and 11, respectively. The claims apply to numerous polypeptides. Each of the polypeptides are independent and distinct because they are structurally and functionally different. Accordingly, these claims are subject to restriction under U.S.C. § 121. Upon election of a particular Group, in this case Group I, applicants were additionally required to elect a single polypeptide of SEQID NO:2, 4, 6, 8, 10 and 12 encoded by the nucleic acid of SEQ ID NO:1, 3, 5, 7, 9 and 11, respectively.. This requirement was not to be constructed as a requirement for election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

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Therefore each polypeptide of SEQID NO:2, 4, 6, 8, 10 and 12 constitutes an independent and patentably distinct invention. Searching the inventions of Groups I-III would impose a serious search burden on the Examiner. The inventions of Groups I-III have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the different polypeptides are not coextensive. Groups I and II encompasses seven structurally and functionally different proteins. An examination of the materially different, patentably distinct inventions in a single application would constitute a serious undue burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Further Applicant is required to cancel or amend elected claims pertaining to non-elected invention, i.e. relating to SEQ ID NOs: 3-12.

Claims 9 and 10 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. **Objections**

The disclosure is objected to because of the following informalities:

A) An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification, following the Title (37 CFR 1.78) as well as the relationship of instant application to the parent. Specific reference to the prior application(s) is not in the first sentence of the specification following the Title. Appropriate correction is required. Further, parent application 09/162,021 is now U.S. Patent

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Number 6,337,391, issued January 8, 2002; application 09/715,538 was abandoned 6/26/03; application 08/622,738 was abandoned 7/1/02, and must be indicated as such.

3. ***Sequence Rules Compliance***

This application fails to comply with the sequence rules, 37 CFR 1.821-1.825. Nucleotide and polypeptide sequences must be identified with the corresponding SEQ ID NO. Title 37, Code of Federal Regulations, Section 1.821 states "reference must be made to the sequence by use of the assigned identifier", the identifier being SEQ ID NO. Sequences in Figures 4, 16, 19, 22, 25 and 28 must be identified by their corresponding SEQ ID NO:. Said Figures contain both polypeptide and polynucleotide sequences, but are identified by a single SEQ ID NO: in each case. The polypeptides in each of said Figures also requires a SEQ ID NO:. Compliance with sequence rules is required.

Claim Rejection, 35 U.S.C. 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 is indefinite because it is not clear what protein is purified from a clone deposited under ATCC No:209602. It is not clear if the clone encodes one

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or more polypeptides that can be isolated. Further the polypeptide cannot be purified from the clone deposited under ATCC No:209602, clones are polynucleotides which encode polypeptides. The claim does not include the essential method steps which disclose how the polypeptide is purified from the clone.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polypeptide molecule having at least 80% or 90% identity with the polypeptide disclosed in SEQ ID NO:2 (encoded by the polynucleotide of SEQ ID NO:1), which is sensitive to changes in Ca^{2+} , Mg^{2+} and NaCl, allows fish to sense Ca^{2+} , Mg^{2+} and NaCl concentrations and adapt to said changing concentrations by altering water intake, water absorption, urine output, modulate the percentage of total fat, protein and moisture of muscle, does not reasonably provide enablement for other polypeptide. The, specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While the person of ordinary skill in the art would, in light of the specification be able to isolate the polypeptide of SEQ ID NO:2, an aquatic

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polyvalent cation-sensing receptor, said receptor having been shown to be a functional ion sensor in fish, where its sensitivity is modulated by alterations in extracellular Ca^{2+} , Mg^{2+} and NaCl concentrations. The scope of the claims encompass the isolated polypeptide senses all ion concentrations, which is not supported by the specification or prior art. The claimed polypeptide has not been shown to sense other ions, except those disclosed above. Therefore the scope of the polypeptide is limited to those ions that modulate its function in fish as disclosed above.

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal Basi *NMB*
Art Unit 1646
12/24/2004

Michael D. Pak
MICHAEL PAK
PRIMARY EXAMINER